UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,698	09/08/2006	Klaus Hellerbrand	341358	9077

25764 7590 08/27/2010

FAEGRE & BENSON LLP
PATENT DOCKETING - INTELLECTUAL PROPERTY
2200 WELLS FARGO CENTER
90 SOUTH SEVENTH STREET
MINNEAPOLIS, MN 55402-3901

EXAMINER	
HEYER, DENNIS	
ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
08/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

djohnson2@faegre.com
rhale@faegre.com
PatentDocketing@Faegre.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,698	HELLERBRAND ET AL.	
	Examiner	Art Unit	
	DENNIS HEYER	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/6/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Applicant's remarks filed June 17, 2010. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53 are currently pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 6, 2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Withdrawn Rejections

Claim rejections – 35 USC § 112 – 2nd Paragraph

The rejection of Claims 1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention is withdrawn in response to Applicant's arguments. Applicant has persuasively argued that "the language of claim 1 is clear and readily understood by one of ordinary skill in the art and that "when Claim 1 is read in a technically sensible manner and the words as used are interpreted as they are read by a skilled artisan, it is clear that the order of steps (b) and (c) may be reversed" (Remarks, page 5, 2nd paragraph).

Claim rejections – 35 USC § 112 – 1st Paragraph

The rejection of Claims 1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement is withdrawn in response to Applicant's arguments. Applicant has persuasively argued that Claim 1 is enabled because "a skilled artisan understands what is technically meant by the reversal of the order to steps (b) and (c) and would clearly be able to perform the two alternative orders of addition" (Remarks, page 5, 2nd paragraph).

Maintained Rejections

Claim rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6, 8, 11 – 12 and 16 – 17 *remain* rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005; previously cited in the Office Action mailed November 27, 2009) in view of Talalay in US patent 4,063,367 (published: December 20, 1977).

Song teaches a medical device comprising a substrate, a therapeutic agent containing region over the substrate which comprises a therapeutic agent an antioxidant (a coating) as well as methods of making said coated devices (Abstract)

Song teaches providing a solution comprising a solvent, a therapeutic agent and an antioxidant, contacting the solution with a medical device substrate and then removing the solvent from the solution to form a therapeutic-agent-containing region (Abstract). Song teaches 'dipping techniques' (equivalent to inserting the device into

the solution) as a preferred solvent-based technique for contacting the device with a solution (instant Claim 1, step c) Song teaches the solution contacting the medical device substrate comprises a therapeutic agent (a therapeutic substance; Abstract; instant Claim 4).

Instant Claim 6 is drawn to immobilization of the pharmaceutically active substance to an inorganic or organic bioresorbable material. Song teaches that the process of contacting the substrate (the previously formed polymer layer) with a solution containing a therapeutic agent (pharmaceutically active substance) results in said agent being "imbibed by the polymer". One of ordinary skill would reasonably construe the process of "imbibing" (defined as: to take in, absorb) to meet the limitation of 'immobilized' as defined in paragraph [0053] of the instant specification. Song also teaches that the imbibing (immobilization) may occur within a bioresorbable material including polypeptide biopolymers coatings (paragraph [0039]).

Song teaches the solution contacting the medical device comprises non-active ingredients, specifically, a polystyrene-polyisobutylene block copolymer (page 13, Example 3, paragraph [0050]; instant Claim 8). Song teaches the solution contacting the medical device is an organic solvent, tetrahydrofuran (page 13, Example 3, paragraph [0050]; instant Claim 12). Song teaches the solution contacting the medical device contains an antioxidant, said antioxidant comprising BHT, BHA or tocopherol (Abstract, step a (iii), paragraph [0009], see also, page 13, Example, paragraph [0050]; instant Claim 14). Song teaches that the medical device may be a stent (page 13, Example 3,

paragraph [0050]) and that the medical device includes any coated substrate which can comprise, for example, metal (page 3 – 4, paragraph [0020]) (instant Claims 16 and 17).

Claim 1, step (d) recites the limitation that the device is coated by "starting isothermal drying of the device while the device remains held within the solution held within the container, thereby removing the volatile components from the solution of the coating substance".

Song teaches the step of drying a coated medical device in an oven but does not expressly teach the process of isothermal drying as recited in instant Claim 1, step (d), or the limitation of instant Claim 11, wherein the container from which the solvent is removed becomes the packaging container for the device.

Talalay teaches a method for drying liquid contained in a container comprising a biologically active liquid solid composite comprising the step of passing a stream of dry air over said container in order to evaporate the liquid from said container (Claims 1 and 3). Talalay does not use the term 'isothermal drying', however, Talalay teaches a process in which the temperature is held constant (column 3, lines 56 – 58) and thus the drying process of Talalay is considered to fall within the scope of the process of 'isothermal drying' disclosed on page 20, lines 7 - 25 of the present specification. Tally teaches the containers are subsequently subjected to a vacuum to complete the drying operation (removal of liquid), filled with an inert gas and then sealed (column 2, lines 2 – 7; see also Claims 3 and 4). Talalay teaches that the process of drying the biologically active material and sealing the receptacles ensures a long shelf life (column 2, lines 10 – 13). Talalay teaches that the vacuum step of the process removes residual moisture

from the containers as well as oxygen and airborne contaminants. Accordingly, one of ordinary skill would have recognized that the drying process of Talalay teaches a container that becomes the packaging container for the solid material, as recited in instant Claim 11.

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to modify the drying method for the coated medical device of Song using the isothermal drying process taught by Talalay wherein the container becomes the packaging container for the device . One would have been motivated to do so because Talalay teaches the method allows one to seal the receptacle (container) following removal of moisture (liquid) and thus ensure a longer shelf life.

Further, one would have been motivated to remove volatile components from the coated medical device of Song by carrying out the isothermal drying method taught by Talalay because Song teaches that it may be beneficial to maintain a therapeutic agent coated onto a medical device in a non-oxidizing environment during the course of its formation (page 12, paragraph [0046] and [0047]) and, that subsequent to it's formation, it may be beneficial to place the coated medical device into packaging that has been evacuated or into which an inert gas has been introduced in order to maintain a non-oxidizing environment (paragraph [0047]). Accordingly, one would have been motivated to modify the drying method of Song with the isothermal drying method of Talalay in which the container becomes the packaging container for the device because Talalay teaches said method extends the shelf life of a therapeutic agent and provides an inert (oxygen-free and thus anti-oxidizing) environment.

Claims 9, 13, 48 and 52 – 53 *remain* rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005) in view of Talalay in US patent 4,063,367 (published: December 20, 1977), as applied to Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17 above, and further in view of Kohnert *et al.* in WO 2003/043673 (publication date: May 30, 2003; previously cited in the Office Action mailed November 27, 2009).

As noted in the 103(a) rejection above, the combination of Song and Talalay renders obvious the method recited in instant Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17.

Song in combination with Talalay do not teach a coating substance comprising calcium phosphates (instant Claim 9), or the device being calcium phosphate or β-tricalcium phosphate (instant Claims 52 – 53). The references also do not teach an acidic aqueous contacting solution (instant Claim 13), or that the method of instant Claim 1 provides a homogeneous distribution of the coating on the device (instant Claim 48).

Kohnert teaches devices having osteoconductive and osteoinductive properties (Title) comprising a carrier containing calcium phosphate wherein said carrier is homogeneously coated with protein (Abstract). Kohnert teaches a method for preparing said devices comprising providing a solution comprising an osteoinductive protein and a buffer and contacting the solution with a carrier containing calcium phosphate.

Kohnert teaches that the contacting solution comprises a carrier containing calcium phosphate (page 6, 3rd paragraph; instant Claim 9). Kohnert teaches that the device may be made of calcium phosphate or β-tricalcium phosphate (Claim 11, instant Claims 52 and 53). Kohnert teaches that the contacting solution comprises a buffer, and that, preferably, the preferred pH is between 4 and 6 (page 8, paragraphs 3 and 4), which meets the limitation of the instant Claim that the contacting solution be an aqueous acidic solution (instant Claim 13).

Instant Claim 48 is drawn to a homogeneous distribution of the coating on the device. Kohnert teaches a method that provides a homogeneous coating on the surface of the device (page 6, paragraph 3 to page 7 paragraph 1, in particular step (c)) and teaches that an advantage of the present invention is the homogeneous coating which is achieved during the coating process (page 7, paragraph 4).

One would have been motivated to modify the method of coating the device of Song and Talalay, when the solution is an acid aqueous solution (preferably pH 4 - 6) because Kohnert teaches that said pH ranges prevent the precipitation of the bone morphogenic member protein (BMP) family member, GDF-5, from solution and insures the device achieves a homogeneous coating (page 7, paragraph 3 and 4) as nonhomogeneous coatings can lead to decreased osteoinductive properties (page 6, 2nd paragraph). Therefore, Kohnert provides specific motivation to optimize the nature of the coating solution (from an organic solvent to an aqueous acidic solution at pH 4 – 6) of Song by teaching that the protein-derived therapeutic agents taught by Song,

which include BMP protein (Song, paragraph [0033]), will remain in solution at an aqueous solution at pH 4 – 6.

One would have been motivated to modify the method of coated a medical device rendered obvious by the combination of Song and Talalay with a bioresorbable material such as calcium phosphate and β-tricalcium phosphate because Kohnert teaches that said materials are effective bone-replacement materials (page 1, paragraph 2) and thus are art-recognized as components of medical devices.

Thus it would have been *prima facie* obvious to one of ordinary skill in the art, to modify the method of Song and Talalay with the teachings of Kohnert, at the time the invention was made, to arrive at the instantly claimed, homogeneously coated medical device with a predictable and reasonable expectation of success.

Claim 15 *remains* rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005) and Talalay in US patent 4,063,367 (published: December 20, 1977), as applied to Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17 above, and further in view of Lee *et al.* in US patent 5,571,523; published November 5, 1996; previously cited in the Office Action mailed November 27, 2009)

As noted in the 103(a) rejections above, Song in combination with Talaly renders obvious the method of instant Claim 1. The references render obvious that the solution contacting the medical device comprises an antioxidant (such as BHT, BHA or tocopherol, instant Claim 14), but does not expressly teach methionine as the antioxidant.

Regarding instant Claim 15, Lee *et al.* teach a method for inhibiting arteriosclerosis by contacting an artery with an apoptosis-inducing amount of an antioxidant (Abstract) in which methionine is a preferred antioxidant (column 1, lines 37 – 43, Claim 7). Lee teaches that one means for locally delivering the antioxidant is by providing (coating) the antioxidant on the surface of a vascular catheter (a medical device) which contact the wall of a blood vessel (column 1, lines 64 – 67). Thus, it would have been *prima facie* obvious to one skilled in the art, at the time the invention was made, to modify the method rendered obvious over Song and Talalay and use methionine as an antioxidant in place of tocopherol, BHA or BHT on a coated medical device, such as a stent or catheter. One would have been motivated to do so because methionine is effective at inhibiting arteriosclerosis and has been taught by Lee that a means of delivering methionine to a blood vessel is *via* an implantable medical device.

Claim 51 *remains* rejected under 35 U.S.C. 103(a) as being unpatentable over Song in WO 2005/016399 A1 (filing date: August 11, 2004, published: February 24, 2005) and Talalay in US patent 4,063,367 (published: December 20, 1977), as applied to Claims 1 – 5 and 8, 11 – 12, 14 and 16 – 17 above, and further in view of Gao *et al.* in US patent 6,113,993 (published: September 5, 2000; previously cited in the Office Action mailed November 27, 2009).

As noted in the 103(a) rejection above, Song in combination with Talalay render obvious the method of instant Claim 1. Song in combination with Talalay render obvious a method for coating implantable medical devices in which the coated substrate

comprises metal (paragraph [0020]) but do not expressly teach a device made of titanium or a titanium alloy as recited in instant Claim 51.

Gao teaches a method of coating an implant with a calcium phosphate compound on a titanium substrate (Abstract). Gao teaches that orthopaedic implants are commonly made of titanium alloy because of its corrosion resistance to body fluids. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to adapt the method of coating a medical device rendered obvious over Song and Talalay to a device made of titanium. One would have been motivated to do so because implants are commonly made of titanium alloys to gain the benefit of their corrosion resistance to body fluids.

Response to Arguments

Applicant's arguments filed June 17, 2010 with respect to the rejections under 35 U.S.C 103(a) have been fully considered but are found not to be persuasive. Applicant argues that "Talalay does not report an isothermal drying step [recited in step (d) of amended Claim 1], there is no basis to combine Song with Talalay, and this combination does not predict that a device may be coated according to the method now recited in the pending claims" (Remarks, pages 5 – 6, bridging paragraph).

Applicant argues that "Talalay cannot be subsumed under the description of isothermal drying as provided in the specification of the present application at page 20" (Remarks, page 6, 2nd paragraph). Applicant argues that "Talalay reports that warm dried air with a temperature of approximately 65°C is applied (see column 3, lines 56-

58) which is then dehumidified (see column 3, lines 49-60)" and "that this high temperature is far beyond the temperature applied in the current isothermal drying". Applicant argues that "drying applies an ambient temperature of about 25°C (see the present specification at page 23, lines 20-22) in order to not inactive the biologically active coating substance" and that "in an isothermal drying process the air is not dehumidified", "rather the air is cooled down by means of an ice-cooled condenser (see the present specification at page 20, lines 6' 11)". Applicant states that "Talalay reports that the air flows along the container with high velocity (see, e.g., claim 1 of Talalay)" which, Applicant argues "would be counterproductive in the current claimed method, since it would disturb the homogenous coating of the coating substance". Applicant argues that while Talalay reports that the air pressure is decreased after the drying process takes place", "the isothermal drying according to the present invention is carried out under reduced pressure (see the present specification at page 20, line 12)" (Remarks, page 6, 2nd paragraph).

These arguments are not found to be persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the temperature of the isothermal drying, the humidity, the velocity of the air flow and the changes in air pressure *after* the drying process takes place) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is further noted that, the description on page 20 of the present specification of 'isothermal drying' to which Applicant relies in the arguments above is not limiting. For example the description of isothermal drying does not require room temperature but states instead "the temperature of the solution is hold at a defined temperature preferably by using a temperature regulated shelve where the product is located on" (page 20, lines 12 – 15, present specification; emphasis added).

Further, the argument that the higher temperatures of Talalay risks inactivating a biologically active coating substance is not found to be persuasive because Talalay is also directed to a method of drying biologically active substances and thus one of ordinary skill would not be dissuaded from applying temperatures above room temperature using isothermal drying.

Applicant argues that "the result of the drying process of Talalay is a dried biologically active material adhered to the walls of the container". "Applicant submits that this is clearly the opposite of what the present invention teaches and for what the claimed method provides: a biologically active material coated on a device (and not on the walls of the coating container)" (Remarks, page 7, 1st and 2nd paragraphs).

This argument is not found to be persuasive because first, as noted above, again applicant is citing features (the structure conferred by the biologically active material and the container) that allegedly distinguish Talalay from the present invention but which are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further,

Applicant's argument that the result of the drying method of Talalay does not provide a material coated on a device is not found to be persuasive because one cannot show nonobviousness by attacking references individually (Talalay) where the rejections are based on combinations of references (Song in view of Talalay). See *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the present case, Song teaches a coated medical device and the rejection is drawn to modifying Song with the drying method of Talalay to predictably provide the coated device by the claimed coating method.

Applicant argues that "as previously explained in the response of January 27, 2010, there is no discussion within Song that the drying process using an oven is less than optimal or otherwise in need of improvement, and thus one of ordinary skill in the art would not be motivated to alter Song's drying process. Indeed, a mere statement, as set out in the Office Action, that the claimed invention is within the capabilities of one of ordinary skill in the art, is not sufficient by itself to establish a prima facie case of obviousness. Instead, there must be some articulated reasoning with some rational underpinning to support a conclusion that the pending claims are unpatentable. This prerequisite reasoning has not been provided by the Examiner" (Remarks, page 7, 4th and 5th paragraphs).

This argument is not found to be persuasive because the Examiner has articulated reasons as to why one of ordinary skill would have been motivated to modify the oven drying method of Song to coat a medical device. As noted on page 10, 2nd paragraph the Office Action mailed March 17, 2010, one would have been motivated to

modify Song with Talalay because the drying method Talalay allows one to seal the container following removal of moisture (volatiles) and thus ensure a longer shelf life. Further support for said modification is found in Song who teaches the advantage of maintaining a coated medical device in a non-oxidizing environment and to subsequently place said coated device into a packaging container evacuated or into which an inert gas is introduced (Office Action, page 11, 1st paragraph). Thus Song clearly suggests and provides motivation to modify the oven drying method to one which dries the device in the packaging container in order to prevent oxidation, i.e. the drying method of Talalay.

Applicant argues that combining the teachings of Song with Talalay would not lead to a predictable result. Applicant argues that "the coating substance result of the present invention is not predicted by combining the teaching of Song with that of Talalay". Applicant states that "Song reports drying of a coated implant with an oven, while Talalay reports a method for drying a solid-liquid composite with the aim of dehydrating the composite in order to make it more stable" and concludes that "[t]hus, the method of Talalay is not suitable to dry a coated substance on a device" (Remarks, page 7, final paragraph).

This argument is not found to be persuasive because in response to applicant's argument that drying a solid-liquid composite (Talalay) is not suitable to dry a coated substance on a device (Song), the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or

all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As noted above, the Examiner has provided motivation to modify the drying method of Song with Talalay (extend the shelf life, Talalay; and obtain the benefit of placing a coated medical device into packaging to maintain a non-oxidizing environment; Song).

Applicant argues that "the device coated in accordance with the current claimed method is not dried for the purpose to store it over a long shelf life, it is dried to complete the coating of the device" and that "the device coated in accordance with the present claimed method is not dried with the aim of dehydrating a biologically active ingredient. Rather, it is dried with the aim of removing volatile components of the coating substance solution". Applicant argues that "the method of Talalay is based on the drawbacks of the prior art and thus Talalay aims at stabilizing biologically active materials, i.e., materials that contain moisture in order to increase their shelf life".

This argument is not found to be persuasive because in response to applicant's argument that the coating method Talalay is drawn to extending shelf life and removing moisture from the biologically active material the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

Claims 1, 4, 6, 8 – 9, 11 – 17, 48 and 51 – 53 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached at (571)272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628